UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

GUARDANT HEALTH, INC.,

Plaintiff,

v.

NATERA, INC.,

Defendant.

Case No. 21-cv-04062-EMC

PUBLIC/REDACTED VERSION

ORDER GRANTING IN PART AND DENYING IN PART PLAINTIFF'S MOTION TO DISMISS OR STRIKE AMENDED COUNTERCLAIMS

Docket No. 95

Plaintiff Guardant Health Inc. ("Guardant") filed this action against Defendant Natera, Inc. ("Natera") alleging that Natera launched a "campaign of false and misleading advertising directed at" its new product—"Reveal"—a liquid biopsy cancer assay for early-stage colorectal cancer. *See* Docket No. 1 ("Compl.") ¶ 1. Natera then filed amended counterclaims ("Amended Counterclaims") against Guardant, alleging that Guardant has engaged in a "campaign of false and misleading commercial statements regarding the performance of [Reveal]." *See* Docket No. 90 ("Am. Countercl.") ¶ 3.

Pending before the Court is Guardant's motion to dismiss or strike Natera's Amended Counterclaims. *See* Docket No. 95 ("Mot."). For the following reasons, the Court **DENIES** Guardant's motion to dismiss Natera's Counts I–IV and **GRANTS** its motion to dismiss or strike Natera's Counts V–VIII without prejudice.

I. BACKGROUND

A. Factual History

A detailed factual background of this case can be found in the Court's order denying Natera's motion for a preliminary injunction. Docket No. 86 ("PI Order") at 1–2. For the

purposes of this motion, the following facts are relevant. The parties offer competing diagnostic tools for colorectal cancer ("CRC")—Guardant's "tumor-naïve" Reveal and Natera's "tumor-dependent" Signatera assay. Am. Countercl. ¶ 28. Guardant bases its contentions that Reveal works on "[p]eer reviewed data published by Parikh, et al., in the journal of Cancer Research" (the "Parikh Study"). Compl. ¶ 20; *see* Aparna R. Parikh et al., *Minimal Residual Disease Detection using a Plasma-Only Circulating Tumor DNA Assay in Colorectal Cancer Patients*, 021 Clinical Cancer Res. OF1, *available at* https://clincancerres.aacrjournals.org/content/early/2021/06/22/1078-0432.CCR-21-0410.full-text.pdf. The senior authors of the study are Dr. Aparna Parikh and Ryan Corcoran who are both faculty at the Harvard Medical School and members of the Department of Medicine, Division of Hematology and Oncology, Massachusetts General Hospital ("MGH") Cancer Center. Docket No. 90-1 (the "Parikh Study" or the "Study") at OF1. 38 of the 43 authors who undertook the study are affiliated with MGH and the remaining five authors are Guardant personnel. *Id.* at OF8.

The Parikh Study evaluated if a plasma-only minimal/molecular residual data ("MRD") assay, *i.e.*, Reveal, can detect circulating tumor DNA ("ctDNA") "with clinically meaningful specificity and sensitivity." *Id.* at OF2. "Specificity" "measures the percentage of negative results that are correctly identified among non-recurring patients." Am. Countercl. ¶ 34. "A test with high specificity is more likely to identify the absence of cancer in a blood sample when no MRD is in fact present, as verified by a clinical 'gold standard' (*e.g.*, the patient remains recurrence-free or progression-free)." *Id.* "Sensitivity" "measures the percentage of positive results that are correctly identified among recurring patients, as verified by a clinical 'gold standard' (*e.g.*, subsequent clinical or radiographic recurrence)." *Id.* ¶ 33. "A test with high sensitivity is more likely to detect the presence of ctDNA in a blood sample in which MRD is actually present." *Id.* The Study allegedly "shows that Reveal offers 91% recurrence sensitivity (i.e., ability to identify which patients will recur based on ctDNA detection) and 100% positive predictive value for recurrence (i.e., all patients Reveal identified as having a 'positive' ctDNA test result later recurred)." Compl. ¶ 20.

The Study utilized the banked blood samples of patients from MGH collected at various

time points from August 2016 to May 2019. Parikh Study at OF1, OF2, OF7. It presented data at a "landmark" timepoint, "defined as the plasma specimen drawn approximately 1 month after completion of definitive therapy (surgery alone or completion of adjuvant therapy for patients who received adjuvant treatment)." *Id.* at OF2. It assessed data at "longitudinal timepoints," "defined by patients who had subsequent draws after their 'landmark' timepoint." *Id.* And it assessed data from "surveillance" draws, defined as "a draw obtained within 4 months of clinical recurrence." *Id.* The "surveillance" draws were purportedly defined based on methods employed by a separate study, the Reinert study, which evaluated the efficacy of Natera's product, Signatera.[1] *Id.* "Patients without clinical follow-up available were excluded from the study. Analysis was completed for patients with at least 1 year of follow-up and for the overall eligible cohort." *Id.* at OF3.

The Parikh Study reported that, "Landmark recurrence sensitivity and specificity were 55.6% and 100%. Incorporating serial longitudinal and surveillance (drawn within 4 months of recurrence) samples, sensitivity improved to 69% and 91%." *Id.* at OF1. Specifically, of 70 landmark evaluable patients—*i.e.*, patients who had their plasma specimen drawn approximately one month after completion of definitive therapy—17 patients had detectable ctDNA. *Id.* at OF4. Of the 17 patients with detectable ctDNA, 15 patients recurred. *Id.* The Parikh Study reports that landmark recurrence specificity was 100%, however, because the two patients, who had detectable ctDNA but did not recur, had a follow-up of less than one year and the Study only accounted for patients with at least one year of follow-up. *Id.* Therefore, when accounting for patients with at least one year of clinical follow-up, 15 of 15 patients with detectable ctDNA recurred, meaning the landmark recurrence specificity was 100%. *Id.* Additionally, of the 49 patients without detectable landmark ctDNA, 12 patients recurred. *Id.* In other words, of the 27 patients who recurred, Reveal detected ctDNA in 15 of them and therefore the landmark recurrence sensitivity was 55.6% and the specificity was 100%. *Id.*; *see also id.* at OF6, Fig. 3b.

[1] Reinert T., Henricksen TV, Christensen E. et al. study entitled "Analysis of Plasma Cell-Free DNA by Ultradeep Sequencing in Patients with Stages I to III Colorectal Cancer," published in JAMA Oncology in 2019. Am. Countercl. ¶ 29.

Furthermore, after "incorporating serial longitudinal samples" the sensitivity for recurrence prediction improved to 69% and after incorporating "surveillance" samples the sensitivity improved to 91%. *Id.* at OF1. The Parikh Study explains that "sensitivity for recurrence prediction can be improved with longitudinal plasma monitoring." *Id.* Nine of 14 patients "who recurred despite no detectable landmark ctDNA or who lacked landmark draws had at least one evaluable longitudinal specimen at a later timepoint." *Id.* By integrating the longitudinal specimens, the sensitivity improved to 69% because of the 29 patients who recurred, Reveal detected ctDNA in 20 patients. *Id.* at OF6, Fig. 3b. The Parikh Study also "assessed performance in patients with evaluable 'surveillance' draws, defined as a draw within 4 months of clinical occurrence, and observed that sensitivity improved to 91%." *Id.* at OF4. Seven of the 29 patients who recurred did not have a surveillance draw. Of the 22 patients who recurred and had a surveillance draw, Reveal detected ctDNA in 20 out of 22 patients, and therefore the sensitivity improved to approximately 91% under a "surveillance" analysis. *Id.* at OF6, Fig. 3b.

After it was peer-reviewed, the Parikh Study was published in the journal Clinical Cancer Research, which is published by the American Association for Cancer Research. *Id.* at OF1. Guardant has referred to the results of the Parikh Study in its advertisements to doctors, clinicians, and biopharmaceutical companies as well as communications with stakeholders regarding Reveal. *See, e.g.*, Docket No. 90-2 at 18 (conference presentation); Docket No. 90-3 (press release about Reveal's commercial launch).

B. Procedural History

On May 27, 2021, Guardant filed the instant action seeking to enjoin Natera "from continuing to make or disseminate false or misleading statements about the performance of Reveal and Signatera; to require Natera to retract, remove, and correct these false and misleading advertising claims; and to recover damages." Compl. ¶ 4. Guardant raises four causes of action in its Complaint: (1) false advertising in violation of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B); (2) false advertising in violation of section 17500 of the California Business and Professions Code, Cal. Bus. & Prof. Code §§ 17500–17509; (3) unlawful trade practices in violation of section 17200 of the California Business and Professions Code, Cal. Bus. & Prof. Code §§ 17200–17210;

and (4) common law unfair competition. *Id.* ¶¶ 56–81.

On June 2, 2021, Guardant filed a motion for a temporary restraining order ("TRO") seeking to enjoin Natera from making derogatory statements about Reveal at the American Society of Clinical Oncology ("ASCO") annual meeting. Docket No. 12 ("First TRO Mot."). By the Court's instruction, the parties filed a joint statement under seal on June 5, 2021, where they agreed not to make any direct head-to-head comparisons of the products until the Court had a chance to rule on Guardant's forthcoming motion for a preliminary injunction. *See* Docket No. 25-3 ("Joint Statement").

On July 20, 2021, Natera filed its own TRO motion, alleging that Guardant is "disseminating false and misleading statements inflating the performance of Reveal . . . as part of a sweeping new 'Product Launch' sales campaign commenced on or around July 15, 2021." *See* Docket No. 62 ("Second TRO Mot.") at 1. Specifically, Natera challenged the veracity of the following statements from a July 15, 2021 advertising email from Guardant's sales team to physicians around the country:

> "Reveal has higher specificity than CEA [carcinoembryonic antigen tests, which are the current standard of care] in the surveillance setting;
>
> Reveal has a 91% sensitivity in the surveillance setting;
>
> Reveal's PPV [positive predictive value] is 100% and can have benefits in patients with stage 2 colorectal cancer, including identifying patients who may benefit most from adjuvant therapy;
>
> and Reveal has a greater lead time for detecting MRD [minimal/molecular residual disease] than current methods."

Id. at 8. It complained that these statements "either lack any support in the Parikh study—the only published study that has ever reported the performance of Reveal in anything approximating a 'surveillance' setting—or severely distort what Parikh actually reported about Reveal," *id.* at 5–8. The Court acknowledged that district courts in the Ninth Circuit have generally issued preliminary injunctions in false advertising and unfair competition cases only when it is clear that the commercial speech at issue is "literally false." PI Order at 8. It denied Natera's motion because it was not clear that Guardant's statements were literally false. *Id.* at 12.

On June 22, 2021, Natera filed its original answer and counterclaims, alleging that Guardant had engaged in a "campaign of false and misleading commercial statements regarding the performance of [Reveal]." *See* Docket No. 48 ("Countercl.") ¶ 3. On August 3, 2021, Guardant filed a motion to dismiss, Docket No. 77, but Natera filed its Amended Answer and Counterclaims on September 7, 2021, Docket No. 90. Natera alleges violations of (1) the Lanham Act; (2) false advertising in violation of California Business & Professions Code § 17500; (3) unlawful trade practices in violation of California Business & Professions Code § 17200; and (4) common law unfair competition. Docket No. 90 ("Am. Countercl.").

In its Amended Counterclaims, Natera challenges, for example, the following statements made in Guardant's marketing materials and communications: (1) claims of 91% longitudinal sensitivity; (2) claims of 100% "surveillance" specificity; (3) comparisons of Reveal's lead time and specificity to the standard of care (CEA) in the "surveillance" context; (4) claims pairing "surveillance" sensitivity with 100% specificity from different analyses; and (5) claims about benefits of Reveal to early-stage patients (collectively, the "Challenged Statements"). Am. Countercl. ¶¶ 45, 51, 56, 69–70, 100–01. On September 21, 2021, Guardant filed the present motion to dismiss Counts I–IV of Natera's Amended Counterclaims and to dismiss or strike Counts V–VIII of the Amended Counterclaims. Docket No. 95. The motion hearing took place on November 19, 2021. Docket No. 119 ("Hearing Tr.").

II. APPLICABLE LEGAL STANDARDS

A. Rule 12(b)(6)

Federal Rule of Civil Procedure 8(a)(2) requires a complaint to include "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). A complaint that fails to meet this standard may be dismissed pursuant to Rule 12(b)(6). *See* Fed. R. Civ. P. 12(b)(6).

To overcome a Rule 12(b)(6) motion to dismiss after the Supreme Court's decisions in *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), a plaintiff's "factual allegations [in the complaint] must . . . suggest that the claim has at least a plausible chance of success." *Levitt v. Yelp! Inc.*, 765 F.3d 1123, 1135 (9th Cir. 2014) (internal

quotation marks omitted). The court "accept[s] factual allegations in the complaint as true and construe[s] the pleadings in the light most favorable to the nonmoving party." *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008). But "allegations in a complaint . . . may not simply recite the elements of a cause of action [and] must contain sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively." *Levitt*, 765 F.3d at 1135 (quoting *Starr v. Baca*, 652 F.3d 1202, 1216 (9th Cir. 2011)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (quoting *Twombly*, 550 U.S. at 556).

If the court dismisses pleadings, it "should grant leave to amend even if no request to amend the pleading was made, unless it determines that the pleading could not possibly be cured by the allegation of other facts." *Lopez v. Smith*, 203 F.3d 1122, 1127 (9th Cir. 2000).

B. Rule 9(b)

Claims sounding in fraud or mistake are subject to the heightened pleading requirements of Federal Rule of Civil Procedure 9(b), which requires that a plaintiff alleging fraud "must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). To comply with this heightened pleading standard, the plaintiff must allege the "who, what, when, where, and how" of the alleged fraud. *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003). "The plaintiff must set forth what is false or misleading about a statement, and why it is false." *Id.*

Although the Ninth Circuit has not definitively spoken as to whether Rule 9(b) applies to Lanham Act claims, "the better reasoned [district court] authority is that, where a Lanham Act claim is predicated on the theory that the defendant engaged in a knowing and intentional misrepresentation, then Rule 9(b) is applicable." *23andMe, Inc. v. Ancestry.com DNA, LLC*, 356 F. Supp. 3d 889, 908 (N.D. Cal. 2018). The false advertisement allegations in Natera's Amended Counterclaims expressly allege that Guardant knowingly or willfully deceived consumers. *See, e.g.*, Am. Countercl. ¶ 124 ("Guardant made these false and misleading statements knowingly and

willfully."). UCL and FAL claims sounding in fraud are also subject to the Rule 9(b) standard. *See Davidson v. Kimberly-Clark Corp.*, 889 F.3d 956, 964 (9th Cir. 2018). Therefore, the Court will evaluate whether Natera's Lanham Act, FAL, and UCL counterclaims satisfy Rule 9(b).

C. Rule 12(f)

Rule 12(f) only allows a court to "strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). "Immaterial matter is that which has no essential or important relationship to the claim for relief or the defenses being pleaded." *Fantasy, Inc. v. Fogerty*, 984 F.2d 1524, 1527 (9th Cir. 1993) (internal quotation marks omitted), *overruled on other grounds, Fogerty v. Fantasy, Inc.*, 510 U.S. 517 (1994). As indicated by the language of the rule, "'[t]he function of a 12(f) motion to strike is to avoid the expenditure of time and money that must arise from litigating spurious issues by dispensing with those issues prior to trial . . . .'" *Id.* When ruling on a motion to strike, a court views the pleading under attack in the light most favorable to the nonmoving party. *See RDF Media Ltd. v. Fox Broad. Co.*, 372 F.Supp.2d 556, 561 (C.D. Cal. 2005).

III. DISCUSSION

A. Motion to Dismiss Counts I–IV

Guardant moves to dismiss Natera's counterclaims under the Lanham Act and California's false advertising, unfair trade practices, and common law unfair competition statutes ("Counts I-IV"). Mot. at 1. It focuses on the Lanham Act and does not separately argue for dismissal of Natera's California claims. *See* Mot. at 6–24.

1. Lanham Act

A prima facie case under Section 43(a) of the Lanham Act requires the plaintiff to demonstrate that: "(1) the defendant made a false statement either about the plaintiff's or its own product; (2) the statement was made in a commercial advertisement or promotion; (3) the statement actually deceived or has the tendency to deceive a substantial segment of its audience; (4) the deception is material, in that it is likely to influence the purchasing decision; (5) the defendant caused its false statement to enter interstate commerce; and (6) the plaintiff has been or is likely to be injured as a result of the false statement, either by direct diversion of sales from

itself to the defendant, or by lessening of goodwill associated with the plaintiff's product." *Jarrow Formulas, Inc. v. Nutrition Now, Inc.*, 304 F.3d 829, 835 (9th Cir. 2002).

In *Southland Sod Farms*, the Ninth Circuit held that to "demonstrate falsity within the meaning of the Lanham Act, a plaintiff may show that the statement was literally false, either on its face or by necessary implication, or that the statement was literally true but likely to mislead or confuse consumers." *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997). A plaintiff can prove that an advertisement claim based on product testing is "literally false" by either "attacking the validity of the defendant's tests directly or by showing that the defendant's tests are contradicted or unsupported by other scientific tests." *Id.* "If the plaintiff can show that the tests, even if reliable, do not establish the proposition asserted by the defendant, the plaintiff has obviously met its burden" of demonstrating literal falsity. *Id.* In addition, "[w]hen evaluating whether an advertising claim is literally false, the claim must always be analyzed in its full context" and therefore "courts have held that a claim can be literally false 'by necessary implication.'" *Id.* (internal citations omitted).

The court in *Southland Sod Farms* did not have occasion to address whether the test for falsity is altered where the challenged statements relate to a scientific peer-reviewed study. The Second and Fifth Circuits have addressed the issue specifically.

In *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490 (2d Cir. 2013), the Second Circuit considered "when a statement in a scientific article reporting research results can give rise to claims of false advertising under the Lanham Act . . . ." *ONY*, 720 F.3d at 496–98. It created a safe harbor for statements drawn from "conclusions from non-fraudulent data, based on accurate descriptions of the data and methodology underlying those conclusions, [and] on subjects about which there is legitimate ongoing scientific disagreement," holding that these kinds of "statements are not grounds for a claim of false advertising under the Lanham Act." *Id.* at 498. The Second Circuit further explained that disputes about these kinds of statements should not be resolved by courts but by the scientific public:

> "[I]t is the essence of the scientific method that the conclusions of empirical research are tentative and subject to revision, because they represent inferences about the nature of reality based on the results

> of experimentation and observation. Importantly, those conclusions are presented in publications directed to the relevant scientific community, ideally in peer-reviewed academic journals that warrant that research approved for publication demonstrates at least some degree of basic scientific competence. These conclusions are then available to other scientists who may respond by attempting to replicate the described experiments, conducting their own experiments, or analyzing or refuting the soundness of the experimental design or the validity of the inferences drawn from the results. In a sufficiently novel area of research, propositions of empirical "fact" advanced in the literature may be highly controversial and subject to rigorous debate by qualified experts. Needless to say, courts are ill-equipped to undertake to referee such controversies. Instead, the trial of ideas plays out in the pages of peer-reviewed journals, and the scientific public sits as the jury."

ONY, 720 F.3d at 496–97.

However, *ONY* excepted from this general rule of deference disputes about statements made in a peer-reviewed, published study that are "literally false," *i.e.*, where the study at issue was "fabricated" or "fraudulently created." *Id.* at 497. Courts can resolves these kinds of disputes because if "the data were falsified, the fraud would not be easily detectable by even the most informed members of the relevant scientific community." *Id.*

The Fifth Circuit has distinguished the Second Circuit's decision in *ONY* in situations where the challenged statements are directed at customers instead of the scientific community. In *Eastman Chem. Co. v. Plastipure, Inc.*, 775 F.3d 230 (5th Cir. 2014), the Fifth Circuit affirmed an injunction, which permanently enjoined the defendant from distributing a brochure that contained excerpts of a peer-reviewed study, in part because "the Lanham Act prohibits false commercial speech even when that speech makes scientific claims." *Eastman*, 775 F.3d at 233. In contrast to statements made within the academic literature and directed at the scientific community" in *ONY* the plaintiff in *Eastman* "sought to enjoin statements made in commercial advertisements and directed at customers." *Id.* at 236. "In this commercial context, the First Amendment is no obstacle to enforcement of the Lanham Act." *Id.* (citing *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 638 (1985) ("The States and the Federal Government are free to prevent the dissemination of commercial speech that is false, deceptive, or misleading . . . .")). The Fifth Circuit held that "[g]iven the applicable binding precedent, it is of no moment that the commercial speech in this case concerned a topic of scientific debate.

Advertisements do not become immune from Lanham Act scrutiny simply because their claims are open to scientific or public debate. Otherwise, the Lanham Act would hardly ever be enforceable . . . ." *Id.*

The Ninth Circuit has not embraced the deferential approach employed in *ONY*. Nor has it addressed the Fifth Circuit approach in *Eastman Chemical.* In the PI Order, however, the Court relied on *ONY* to deny Natera's motion for a preliminary injunction and the parties address *ONY* in their briefing. As a result, the Court will analyze the motion to dismiss under both the *ONY* and the *Southland Sod Farms* standards.[2]

Guardant relies heavily on the Court's decision to deny Natera's motion for a preliminary injunction to contend that the Court should also dismiss Natera's Amended Counterclaims in the present motion. *See* Mot. at 7, 9. But a motion for preliminary injunction calls for a heightened legal analysis that is not applicable at the pleading stage. Under Rule 12(b)(6), the issue is whether the allegations—taken as true and from which all reasonable inferences are drawn on the pleader's favor—establish a "plausible" claim. *Iqbal*, 556 U.S. at 678; *Twombly*, 550 U.S. at 556. In contrast, for a preliminary injunction, the issue is whether the moving party is likely to succeed on the merits of its claims. *See Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008).

In the PI Order, the Court held that it could not hold that the challenged statements were "clearly false before discovery and expert testimony is taken" at the "early preliminary injunction stage." *Id.* at 12. It also could not determine that Natera was "likely to succeed on its allegations that [Guardant's statements] are false" because there were "compelling reasons to conclude that claims based on the validity of the Parikh Study—or any other peer-reviewed, non-fraudulent scientific study—are likely 'non-actionable' in the context of false advertising." *Id.* at 13. That

[2] Although this Court distinguished *Southland Sod Farms* during the preliminary injunction stage, it acknowledges its applicability here, at the pleading stage. In the PI Order, the Court found that *Southland Sod Farms* "is of limited help in determining at the preliminary injunction stage, where a full record has yet to be developed, as to whether the [Guardant's statements] which are entirely based on the peer-reviewed Parikh Study are literally false." PI Order at 9. *Southland Sod Farms* was distinguishable because it involved an appeal of a summary judgement order where the district court had the benefit of a full record. *Id.* at 9–10. In contrast, at the pleading stage unlike the preliminary injunction stage, Natera does not have to show that the Challenged Statements are "literally false," only that it is plausible that they are "literally false."

said, it held that it was "not prepared to decide that [Guardant's statements] are 'non-actionable'" at the preliminary injunction stage. *Id.* at 12.

Unlike in the PI context, Natera alleges here that the Parikh Study is based on fraudulent data and inaccurate descriptions of the data and methodology. Opp. at 14–21; *compare* PI Order at 11. It claims that Guardant's marketing claims are "wholly unsupported or are based on a study in which Guardant manipulated the methodology and analysis to reach predetermined conclusions"; claims that must be accepted as true and construed in the light most favorable to it at this pleading stage. Docket No. 100 ("Opp.") at 1. For the reasons explained below, Natera's allegations are plausible. *ONY* is inapplicable to Natera's counterclaims that allege that Guardant's statements are unsupported by the Parikh Study and these claims are plausible under *Southland Sod Farms.* As for its claims about Guardant's statements that are based on the Parikh Study, it sufficiently pleads facts to satisfy even the *ONY* standard as well as the *Southland Sod Farms* standard. *Id.* at 14–24.

Given that the Ninth Circuit has not adopted the deferential standard in *ONY*, nor any other circuit, the Court refuses to dismiss Natera's Counts I–IV under Rule 12(b)(6), especially at this early stage of the proceedings where the issue is simply the plausibility of the asserted claims.

2. Incorporation-by-Reference Doctrine

As a preliminary matter, Natera objects to Guardant's repeated reliance on portions of the Thereasa Rich Declaration, Docket No. 68, and Justin Odegaard Declaration, Docket No. 12-2, that are not the basis of its pleadings. Opp. at 8 n.11, 12 n.14. In a motion to dismiss under Rule 12(b)(6), evidence beyond the pleading should generally not be considered. *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 998 (9th Cir. 2018). An exception to this rule is when the document is incorporated by reference into the complaint. *Id.* The incorporation-by-reference doctrine "is a judicially created doctrine that treats certain documents as though they are part of the complaint itself." *Id.* at 1002. The doctrine's purpose is to "prevent[ ] plaintiffs from selecting only portions of documents that support their claims, while omitting portions of those very documents that weaken—or doom—their claims." *Id.* The doctrine "permits a district court to consider documents whose contents are alleged in a complaint and whose authenticity no party

questions, but which are not physically attached to the . . . pleadings." *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003) (internal quotation marks omitted). Such documents may be incorporated "if the plaintiff refers extensively to the document or the document forms the basis of the plaintiff's claim." *Id.* The Ninth Circuit, however, has recently cautioned,

> "[t]he overuse and improper application of judicial notice and the incorporation-by-reference doctrine . . . can lead to unintended and harmful results. Defendants face an alluring temptation to pile on numerous documents to their motions to dismiss to undermine the complaint, and hopefully dismiss the case at an early stage. Yet the unscrupulous use of extrinsic documents to resolve competing theories against the complaint risks premature dismissals of plausible claims that may turn out to be valid after discovery."

Khoja, 899 F.3d at 998.

In this case, Natera did not cite the Odegaard Declaration in its pleadings and therefore it may not be incorporated. And it only cited the Rich Declaration for the proposition that "Guardant also admits, through employee Thereasa Rich, that its claim of 100% surveillance specificity is no more than an estimate." Am Countercl. ¶ 50. Because this statement does not form the basis of Natera's false advertising claims and because Natera cited the declaration only once—not extensively—it may not be incorporated. *See also Synopsys, Inc. v. InnoGrit, Corp.*, No. 19-CV-02082-LHK, 2019 WL 4848387, at *5 (N.D. Cal. Oct. 1, 2019) (denying a request to incorporate-by-reference documents that were filed with the plaintiff's TRO application in part because the complaint did not extensively refer to the documents).

3. Challenged Statements That Are Allegedly Unsupported by the Parikh Study

Natera alleges that several Challenged Statements are literally false because they are unsupported by the Parikh Study. Am Countercl. ¶ 31. For these statements, *ONY*'s deferential standard to scientific statements does not apply because Natera does not challenge the statements directly from the Parikh Study. Instead, it challenges Guardant's marketing statements that are allegedly unsupported by the study. The *ONY* court held that "conclusions [in a scientific study] from non-fraudulent data, based on accurate descriptions of the data and methodology underlying those conclusions, on subjects about which there is legitimate ongoing scientific disagreement . . . are not grounds for a claim of false advertising under the Lanham Act." *ONY*,

720 F.3d at 497. It did not address the question at issue here—whether marketing statements that purport to be based on a scientific study but in fact are not may violate the Lanham Act.

Therefore, in this context, the *Southland Sod Farms* standard applies. "If the plaintiff can show that the tests, even if reliable, do not establish the proposition asserted by the defendant, the plaintiff has obviously met its burden" of demonstrating literal falsity. *Southland Sod Farms*, 108 F.3d at 1139; *see also Eastman*, 775 F.3d at 237 (distinguishing *ONY* where the statements at issue presented a scientific article's conclusions from its case where the statements were not supported by the peer-reviewed study—they transformed "snippets of . . . a paper which never mentions [the plaintiffs] by name . . . into commercial advertisements claiming [the plaintiff's product] is harmful."). And "[e]ven if an advertisement is not literally false, relief is available under Lanham Act § 43(a) if it can be shown that the advertisement has misled, confused, or deceived the consuming public." *Id.* at 1140.

a. Guardant's "Surveillance" Specificity and Sensitivity Statements

Natera adequately pleads that Guardant's "surveillance" specificity and sensitivity claims lack any basis in the Parikh Study and are therefore false and misleading. Opp. at 11. Specifically, Natera challenges (1) the statements of 91% longitudinal sensitivity; (2) the statements of 100% "surveillance" specificity; and (3) the statements pairing "surveillance" sensitivity with 100% specificity from different analyses.

First, Guardant's marketing statements that claim, "[b]y incorporating longitudinal surveillance samples, sensitivity improved to 91%" are allegedly false because the Parikh Study only reported the 91% sensitivity in its "surveillance" analysis, defined as blood draws obtained within four months of clinical recurrence, Opp. at 13 (citing Am. Countercl. ¶ 65); *see* Parikh Study at OF5; *see* Docket No. 90-7 at 3. In contrast, for "longitudinal" sensitivity, the Parikh Study reported that sensitivity improved to 69% from 55.6% based on all longitudinal blood draws, including ones obtained beyond the four months of clinical recurrence. *Id.*; Opp. at 13. For Guardant's marketing statement about longitudinal sensitivity be truthful and supported by the Parikh Study, Natera alleges that it should have referred to the 69% figure and not the 91% "surveillance" sensitivity. Opp. at 13. Because Guardant's marketing refers to "longitudinal"

surveillance samples, a term that arguably implies more than a 4 month surveillance analysis, it is plausible that Guardant violated the Lanham Act because it misleads a substantial portion of the audience of doctors, clinicians, and biopharmaceutical companies to believe that sensitivity improved to 91% based on draws obtained over a longer period of time than four months. Hearing Tr. at 6, 24; *Southland Sod Farms*, 108 F.3d at 1140.

Guardant also uses a different definition of "surveillance" in its marketing materials than the one used in the Parikh Study. The Amended Counterclaims allege that instead of "surveillance" being defined as blood draws obtained within four months of clinical recurrence as in the Parikh Study, Guardant "recommends that clinicians conduct blood draws" only once every three months in the first two years and "once every 6 months in years 2-5 following definitive treatment." Am. Countercl. ¶ 71 (citing Docket No. 90-8); Hearing Tr. at 43. Due to these varying definitions of "surveillance," "Guardant's use of the same term to mean two things" is allegedly "a deliberate attempt to confuse patients and physicians into thinking that the Study's results are in any way relevant to clinical performance." *Id.* Guardant responds that "surveillance" refers in general to post-treatment monitoring, which is consistent with the Parikh Study's stated purpose, to "evaluate the first tumor uninformed, plasma-only ctDNA assay integrating genomic and epigenomic signatures to detect MRD in post-operative colorectal cancer (CRC) patients." *Id.* (citing Parikh Study at OF2). Thus, its use of the term "surveillance" was not false. But the variation in the definition of the term and the disjunction between the definition of "surveillance" used in the Parikh Study and that used in Guardant's marketing raises a factual dispute whether the Challenged Statement "actually deceived or has the tendency to deceive a substantial segment of its audience." *Jarrow Formulas*, 304 F.3d at 835.

Second, Natera challenges Guardant's marketing statements that claim that (1) Reveal has 100% specificity in the "surveillance" context, Docket No. 90-4 at 8; and (2) "[w]ith a higher sensitivity and specificity than CEA [carcinoembryonic antigen tests, which are the current standard of care], Guardant Reveal performs much better than other tools in the surveillance setting and is an actual measure of the cancer in the blood, not a surrogate. Guardant Reveal has a 91% sensitivity in the surveillance setting," Docket No. 90-6 at 2. These statements are allegedly

false and misleading because the Parikh Study did not report "specificity" in connection with the surveillance analysis. "Specificity" accounts for all patients who did not experience a recurrence of cancer. Am. Countercl. ¶ 34. But by the Study's definition of "surveillance"—*i.e.*, blood draws obtained within four months of clinical recurrence—"all patients in the sample group had experienced a recurrence of cancer, and it would be impossible to obtain a false positive within such a group." *Id.* ¶ 47. It would therefore be impossible to have 100% specificity in the "surveillance" context. As for the second statement—that Reveal has a higher sensitivity and specificity than CEA in the surveillance setting—the Parikh Study not only did not report any "surveillance" specificity, it also did not report any CEA data from the "surveillance" cohort. Opp. at 12. As a result, it is plausible that Guardant's statements are false and misleading.

Guardant responds that these two Challenged Statements are true and supported by the Parikh Study. Docket No. 108 ("Reply") at 5. The Study states, "[i]n the current study, specificity was 100% in patients with at least 1-year minimum clinical follow-up, which aligns with specificity of other tumor-informed MRD approaches for colorectal cancer." Parikh Study at OF5. Guardant also contends that the "limitations of CEA testing are well established" and "there is nothing false or misleading in contrasting those limitations to the reported data from the Parikh Study." Reply at 6. For example, the Parikh Study found that sensitivity and specificity of CEA at the landmark timepoint among patients with at least one year of follow-up was only 35% and 80.7%. Parikh Study at OF7, Fig.4. Another paper, referenced in the Parikh Study, the Reinert study reported 69% sensitivity and 64% specificity for a longitudinal CEA analysis. Docket No. 90-14 ("Reinert Study") at 1127.

But these contentions turn again on variations in the definition of "surveillance setting," *i.e.*, whether it constitutes a time period longer than the four months within recurrence cutoff. Natera's allegations that the Challenged Statements violate the Lanham Act are plausible.

Third, Natera challenges Guardant's pairing of the 91% sensitivity "[f]or recurrence detection with surveillance samples" with the 100% specificity "[f]or recurrence detection following completion of definitive therapy" in its marketing presentation at the J.P. Morgan Healthcare Conference. Opp. at 12 (citing Docket No. 90-2 at 18). Guardant's marketing

materials allegedly "exploit and abuse the Study's limited scope in the surveillance analysis (i.e., all patients experienced recurrence) by misleadingly pairing the Study's reported 100% specificity (from the 'landmark' and 'longitudinal' analyses) with its unsupported 91% sensitivity score from a different analysis (the 'surveillance' analysis) . . . ." Am. Countercl. ¶ 51. Guardant responds that its advertisements correctly report the sensitivity and specificity data, as explained above. Reply at 5; *see* Parikh Study at OF5. For the same reasons, however, there is a factual dispute about whether these statements are not supported by the Parikh Study and are capable of deceiving a substantial segment of the audience. *See Southland Sod Farms*, 108 F.3d at 1139–40; *Jarrow Formulas*, 304 F.3d at 835.

b. Guardant's "Lead Time" and "Early-Stage" Statements

In addition, Natera challenges Guardant's reliance on the Parikh Study to compare Reveal's lead time to that of the CEA test and tout benefits of Reveal for "early-stage" CRC patients. Opp. at 11, 13. Guardant advertises that Reveal "improves the management of early-stage [CRC] . . . by detecting recurrence months earlier than current standard-of-care methods like carcinoembryonic antigen (CEA) tests or imaging." Docket No. 90-5 at 1–2 & n.7; *see also* Docket No. 90-6 at 2 (same); Docket No. 90-4 at 6 & n.2 (stating that Reveal "improves management of early-stage CRC patients by: . . . Detecting recurrent disease 5 months sooner than imaging or CEA (carcinoembryonic antigen)" and that Reveal has a "[h]igher sensitivity and specificity than CEA."). The Parikh Study, however, concludes that "CEA values failed to predict recurrence" suggesting that there was no "lead-time" with CEA. *See* Parikh Study at OF7, Fig.4. Consequently, "the Study presents no statistically significant data from which a lead time for CEA could be evaluated in the Study's patient cohort" and therefore "the Study cannot be relied on to support Guardant's comparisons of a lead time for Reveal with that of CEA." Am. Countercl. ¶ 56.

Similarly, it is plausible that Guardant's marketing statements falsely and misleadingly tout benefits of Reveal for "early-stage" CRC patients because the Parikh Study included at least 19% late-stage patients and did not make any conclusions specific to "early-stage" cancer patients. Opp. at 13. For example, Guardant advertises, "For oncologists, the test improves the

management of early-stage CRC patients by detecting circulating tumor DNA (ctDNA) in blood after surgery to identify patients with residual disease who may benefit most from adjuvant therapy." Docket No. 90-15 ("Am. Countercl. Ex. O") at 6; *see also* Docket No. 90-6 at 2 ("Guardant Reveal has two main applications for your early stage (II and III) colorectal cancer patients: After surgical resection to help with post-surgical chemotherapy decisions in stage II low-risk patients" and "In the surveillance setting to reliably identify the recurrence of active disease in CRC patients."). The Parikh Study, however, "contained at least 19% Stage IV CRC patients who do not qualify as "early-stage" CRC patients, *i.e.*, patients in stages I–III, but Guardant "nonetheless continues making claims about early-stage patients based on the Study that had a small patient population, with only a subset of patients being early-stage patients." Am. Countercl. ¶¶ 101–07; Parikh Study at OF3.

Although these exhibits do not cite the Parikh Study for a comparison of lead time or conclusions about "early-stage" cancer patients, the Parikh Study is the implicit source of these statements as it is the only possible source of such comparisons. Opp. at 11. The Ninth Circuit has held that "[t]o demonstrate falsity within the meaning of the Lanham Act, a plaintiff may show that the statement was literally false, either on its face or by necessary implication, or that the statement was literally true but likely to mislead or confuse consumers." *Southland Sod Farms*, 108 F. 3d at 1139 (citing *Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939, 943, 946 (3d Cir. 1993)). Statements are literally false by necessary implication where "the audience would recognize the claim as readily as if it had been explicitly stated." *Aussie Nads U.S. Corp. v. Sivan*, 41 F. App'x 977 (9th Cir. 2002). Guardant contends that nothing in the cited marketing materials "necessarily imply" any reliance on the Parikh Study for either the CEA lead-time or "early-stage" statements. Reply at 4. It also argues that a claim about Reveal does not necessarily have to be based on the Parikh Study because "[d]rug, device, and testing companies often rely on in-house testing and data-on-file." *Id.* at 5. Because the Parikh Study is the only published study on Reveal's characteristics, however, it is plausible that Guardant's marketing materials "necessarily imply" reliance on the Parikh Study for the CEA lead-time and "early-stage" statements even in the absence of an explicit statement. And where a "defendant's ad explicitly or implicitly represents

that tests or studies prove its product superior, plaintiff satisfies its burden [in proving literal falsity] by showing that the tests did not establish the proposition for which they were cited." *Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57, 62–63 (2d Cir. 1992); *see also Southland Sod Farms*, 108 F. 3d at 1139 (citing *Castrol*, 977 F.2d at 62–63).

Furthermore, the Parikh Study does not support Guardant's statements on Reveal's lead-time and "early-stage" benefits. Guardant points to the Parikh Study's conclusion that "CEA values failed to predict recurrence," Parikh Study at OF7, Fig.4, to contend that there was no "lead-time" with CEA and therefore its statement that Reveal outperforms CEA at recurrence prediction is correct. Reply at 5 n.2. But Guardant's statements do not merely claim that Reveal outperforms CEA generally. They specifically state that Reveal detects recurrence "5 months earlier" than CEA even though the Parikh Study does not indicate at what point in time CEA detects recurrence. *See* Docket No. 90-4 at 6 & n.2. Guardant does not point to any part of the Study that shows "statistically significant data from which a lead time for CEA could be evaluated in the Study's patient cohort." Am. Countercl. ¶ 56. As a result, the Parikh Study does not support Guardant's statements comparing Reveal's lead-time with CEA's purported lead-time.

Guardant also argues that the Parikh Study supports its statements about how Reveal benefits early-stage patients because the Study states that "early MRD detection is critical to enable therapeutic decisions during the standard window for adjuvant therapy initiation" and the Study reported that for "landmark" samples drawn one month after completion of definitive therapy, 24% of patients had detectable ctDNA—and within that subgroup, 88% recurred. Parikh Study at OF4; Reply at 5 n.2. But Guardant improperly equates "early-stage" to "early MRD detection." Opp. at 13. "Early-stage" means stage I, II, or III of cancer. Early MRD detection means detecting MRD early on, *i.e.*, a month after completion of definitive therapy. The Study conducted early MRD detection not only for early-stage patients but also for late-stage patients. *See* OF3. Accordingly, Guardant's statements about "early-stage patients" and "lead-time" are arguably unsupported by the Study and plausibly false or misleading. *Southland Sod Farms*, 108 F. 3d at 1139–40.

The Court **DENIES** Guardant's motion to dismiss the counterclaims based on the

allegations that they are unsupported by the Parikh Study and therefore false and misleading.

4. Challenged Statements That Are Based on the Alleged Fraudulent Methodology of the Parikh Study

Natera not only alleges that the Parikh Study does not support several of Guardant's marketing claims, but also that the Parikh Study's data and methodology themselves are fraudulent. Opp. at 14. In particular, the Parikh Study is allegedly fraudulent because (1) the Parikh Study said it looked only at "patients with evaluable 'surveillance' draws, defined as a draw obtained within four months of clinical recurrence" but it included patients with draws outside of four months to improperly boost Reveal's performance, Am. Countercl. ¶¶ 13–14; (2) it said that "ctDNA analysis was performed blinded to the clinical data" but Guardant's internal documents show that Guardant performed ctDNA analysis unblinded to the clinical data, Am. Countercl. ¶ 15; and (3) it said that it was a "single-institution prospective study" but Guardant's internal documents show that Parikh provided samples for analysis by Guardant after the fact and Guardant retrospectively conducted ctDNA analysis, Am. Countercl. ¶ 12.

For these allegations, Natera sufficiently pleads facts to satisfy even the *ONY* standard as well as the *Southland Sod Farms* standard. Opp. at 14 (citing Am. Countercl. ¶¶ 11–16, 60–108). Under *Southland Sod Farms*, Natera can show the literal falsity of Guardant's statements by "attacking the validity of [its] tests directly." *Southland Sod Farms*, 108 F.3d at 1139. And *ONY* permits a Lanham Act claim if a statement made in a peer-reviewed, published study is literally false: where the study at issue was 'fabricated' or 'fraudulently created.'" PI Order at 10 (quoting *ONY*, 720 F.3d at 497); *see also Biolase*, 2014 WL 12579803, at *4 (dismissing claims under *ONY* because they did not "allege that the studies described in the articles weren't actually performed," "that they didn't produce the findings described," that "the articles' data was fraudulent, that the results were fraudulently altered, or that [the defendant] misstated the articles' findings."). Where false advertising claims allege that the study's conclusions are based on inaccurate descriptions of the data and methodology, the claims can be grounds for a claim under the Lanham Act. *ONY*, 720 F.3d at 497. That said, "if the conclusions authors draw from the results of their data could be actionable such claims would be weakest when . . . the authors readily disclosed the potential

shortcomings of their methodology . . . ." *Id.* The *ONY* exception and the *Southland Sod Farms* standard are met here because Natera plausibly pleads that the Parikh Study misrepresented its methodology and Guardant improperly used clinical data to modify the results of the ctDNA analysis that it reported in the Parikh Study. Opp. at 20.

a. "Surveillance" Analysis

First, it is plausible that the Parikh Study is fraudulent because it claimed to only consider "patients with evaluable 'surveillance' draws, defined as a draw obtained within four months of clinical recurrence" but it in fact included patients with draws outside of four months to improperly boost Reveal's performance. Am. Countercl. ¶¶ 13–14, 65–72. Specifically, the "4-month 'surveillance' cut-off" was improperly "applied only to false negative results, where ctDNA was not detected in recurring patients, and not to positive results, where ctDNA was detected in recurring patients." *Id.* ¶ 68. The "longitudinal" analysis detected ctDNA in 20 out of 29 recurring patients, but failed to detect it in 9 recurring patients, meaning these 9 patients were false negatives. *Id.* "Of the 9 false negatives, 7 were excluded from the 'surveillance' analysis on the grounds that they did not have 'surveillance draws' within 4 months of recurrence," however, all 20 positive results from the longitudinal analysis, where ctDNA had been detected in recurring patients, were included as positive results in the 'surveillance' analysis, *whether or not they had 'surveillance' draws* within four months of clinical recurrence." *Id.* (emphasis in original). In other words, the "four-month cut-off was applied *only to exclude false negative results, i.e.,* failures to detect ctDNA in recurring patients, from the surveillance analysis." *Id.* (emphasis in original).

The "exclusion of these 7 false negative patients resulted in a substantial increase in the apparent sensitivity of the analysis from an unimpressive 69% (20/29) in the 'longitudinal' analysis to a much higher 91% (20/22) in the 'surveillance' analysis" and reduced "the total number of patients evaluated from 29 in the 'longitudinal' analysis to 22 in the 'surveillance' analysis." *Id.* ¶¶ 66–67. "Had the Study applied the contrived 4-month 'surveillance' cut-off both to false negative results and to apparent 'true positive' results," the number of relevant patients "would have dropped from 22 to about 16" and "the sensitivity would have been about 14/16 or

87.5%, not 91%." *Id.* As a result, it is plausible that Guardant "falsely concealed the elimination of patient samples" in its marketing materials when Guardant claimed that "[b]y incorporating longitudinal surveillance samples, sensitivity improved to 91%." *Id.*

Contrary to Guardant's contention, Natera does not mischaracterize Guardant's findings. Guardant explains "there is no valid reason for dropping a true-positive result from a sensitivity analysis, regardless of timing; such a true positive result is meaningful to the sensitivity of an assay, if the presence of ctDNA is predictive of recurrence." Mot. at 11–12. In other words, "if a patient never turned positive, but did not have a draw within four months of recurrence, then they were excluded from the analysis." Docket No. 94-9 at 1352. But true positives were not excluded from the analysis. Reply at 13–14. The problem, however, is that the Parikh Study does not disclose this methodology; there is no mention that certain patients with true positive results were included in the "surveillance" analysis even though recurrence occurred after the four-month cutoff. Whether this would tend to deceive a substantial segment of the audience raises a factual issue. *See Jarrow Formulas*, 304 F.3d at 835.

Further, the disclosure of patient data in the Parikh Study does not disabuse the audience from being misled. Guardant contends that all of the data about every patient is disclosed in the Parikh Study, *e.g.*, who had treatment, who had a follow-up, who recurred, and who did not recur, and therefore there is nothing fraudulent about the "surveillance" analysis. Hearing Tr. at 52–55; *see* Parikh Study at OF5, Fig. 2. But Figure 2 in the Parikh Study does not show which patients were included or excluded from the "surveillance" analysis; only the internal email threads reveal that certain patients were excluded. Hearing Tr. at 60–61; *see* Docket No. 94-9 at 1356 ("there look to be 30 pts who recurred in the entire cohort, and we remove 8 of them with the new analysis due to no surveillance timepoint, leaving 22, 20 of whom are 'detected.'"). As a result, it is plausible that Guardant's statements about Reveal's sensitivity are false and misleading because it misrepresents its methodology. *See ONY*, 720 F.3d at 497; *Southland Sod Farms*, 108 F.3d at 1139–40.

Second, the Parikh Study attributed the "surveillance" definition to the Reinert study even though the Reinert study does not contain such analysis. Am Countercl. ¶ 69. For example, the

Parikh Study states that "based on the method employed by Reinert and colleagues, we also assessed performance in patients with evaluable 'surveillance' draws, defined as a draw obtained within 4 months of clinical recurrence." Parikh Study at OF2. But the Reinert study did not define "surveillance" this way, and Guardant does not dispute this. Mot. at 16–17. Instead, Guardant improperly relies on the Rich Declaration and explains that "Reinert's methodology can be reasonably deduced from Figure 7 in [Reinert's] supplemental data. These data show, by and large patients had samples collected every 3–6 months." Mot. at 16. And as a result, four months "is within the reasonable and expected timeframe of surveillance testing intervals." *Id.* at 17. This, however, contradicts Guardant's internal emails to Parikh and Corcoran, the lead Parikh Study authors, where Guardant states that the longitudinal analysis in Reinert "involves censoring patients who don't have a blood draw within 4 [months] of their recurrence." Docket No. 94-8 at 1336. Although MGH also explained that the Reinert paper was "only including patients that had a data point available within 4 months of clinical recurrence," Docket No. 94-10 at 1352, these emails appear to contradict Guardant's explanation in its briefing that the Reinert paper collected samples every 3–6 months. Natera therefore sufficiently pleads that the Parikh Study is fraudulent because it misrepresents its methodology.[3]

Finally, Natera pleads that these alleged methodological falsehoods in the Parikh Study are attributable to Guardant. Opp. at 16–18. For example, Natera alleges that the Parikh Study was funded by Guardant, Am. Countercl. ¶ 7, that Guardant pressured the MGH doctors to adopt its fraudulent analyses, *id.* ¶¶ 66, 70, and that Guardant was involved in designing and performing the sample analyses in a manner that would artificially inflate the results from the Study, *id.* ¶¶ 60–61. Guardant moves to dismiss these claims based on improper factual challenges or disputes about whether the documents on which Natera relies supports its allegations. *See* Mot. at 13–15. But where "the parties provide conflicting interpretations and out-of-context arguments about the

[3] Guardant asserts that even if there was a misconstruction of Reinert, a mere mistake could not amount to fraud or give rise to suspicion of fraud. *See, e.g., Hill v. State Farm Mut. Auto. Ins. Co.*, 166 Cal. App. 4th 1438, 1486 (Cal. App. 2008) ("A mere mistake of judgment is not fraud.") (quotation marks omitted). But the issue here is not whether Guardant made a mistake but whether the Parikh Study improperly failed to disclose its interpretation of the Reinert study's methodology.

import of illustrations and statements in [a document] attached [to the counterclaims]," "these conflicting interpretations serve only to demonstrate a dispute exists . . . These factual matters will need to be established through an evidentiary record after discovery, perhaps at summary judgment." *See Regents of Univ. of Cal. v. St. Jude Med., Inc.*, No. 16-CV-06210-YGR, 2017 WL 2335542, at *2 (N.D. Cal. May 30, 2017).

Because Natera sufficiently pleads that the methodology related to the "surveillance" analysis is fraudulent and because such failure to disclose certain methodology can substantially mislead the audience, it is plausible that the Parikh Study's "surveillance" analysis is fraudulent. *See ONY*, 720 F.3d at 497; *Southland Sod Farms*, 108 F.3d at 1139–40.

b. "Blinded ctDNA Analysis"

Further, the Parikh Study is allegedly fraudulent because it described its methodology as a blinded ctDNA analysis, Parikh Study at OF3, even though it used "information from unblinded patient samples" and repeatedly changed and re-analyzed data post hoc. Opp. at 18; Am. Countercl. ¶¶ 79, 80–88. Natera sufficiently alleges that "through nearly the entire duration of the Study, Guardant had access to clinical data while performing and re-performing the Reveal test" and therefore "at the time Guardant was testing its assay, it already had the 'answer key.'" Am. Countercl. ¶ 15. On "[redacted]" "[redacted]." *Id.* ¶¶ 80, 83–84. A "calling algorithm" interprets genetic data to call a patient positive or negative for ctDNA. *Id.* ¶ 80. Natera also points to several of Guardant's internal documents to show that [redacted]. Opp. at 18; Am. Countercl. ¶¶ 83, 84. In one email thread, a Guardant employee states that "[redacted]" Am. Countercl. ¶ 83 (citing Docket No. 99-8 at 2). In another email thread, another Guardant employee discusses [redacted] *Id.* ¶ 84 (citing Docket No. 99-9 at 2). According to Natera, the only way the Guardant employee knew that these samples were "false negatives" was because the data was unblinded, *i.e.*, they knew that the patients' cancer had recurred. Hearing Tr.

at 64.

Guardant acknowledges that the data was partially unblinded before final analysis but it contends that the "unblinding allowed Guardant to better understand the data" and "did not impact Guardant's methodology." Mot. at 19. It admits that "it continued to make incremental improvements to Reveal's calling algorithm following its January 2019 research launch, and before its commercial launch in February 2021." *Id.* at 20. But Guardant contends that Reveal's algorithm was not impacted by the partial unblinding of an algorithm that objectively "assesses a sweeping array of information to return a 'yes' or 'no' result based strictly on a computational analysis of the data presented." *Id.* Natera alleges, however, that the "[redacted]" Am. Countercl. ¶ 84. Although Guardant further contends that it did not "tweak" Reveal's algorithm to alter results for the Parikh Study samples because it analyzed the samples using "the version of the algorithm that was locked for Reveal's commercial launch," Reply at 20–21, the Court must assume Natera's allegations to be true. In any event, it is notable that Guardant does not address Natera's reliance on certain Guardant emails to show that [redacted]. Natera sufficiently pleads for purposes of the instant motion that the Parikh Study fraudulently described its methodology as a blinded ctDNA analysis.

Natera also alleges that although the Parikh Study's authors "determined that tumor-informed results were better than tumor-naïve results . . . they did not include *any* tumor-informed data in the Study as published in part because 'it would simply invite too much criticism.'" Am. Countercl. ¶ 85 (emphasis in original). By doing so, Guardant allegedly "hid its own comparison of tumor-naïve and tumor-informed tests from clinicians, allowing Guardant to make false and misleading claims regarding performance of the tumor-naïve Reveal test even when their own tests showed better performance for a tumor-informed version of the test." *Id.* But the figure on which Natera relies in its Amended Counterclaims came not from the Parikh Study but from an existing article discussing a different study of different assays. Mot. at 18. The figure was used in internal communications simply to suggest a "format for presenting data."

Natera does not dispute that the figure came from a separate study but it asserts that its

claim is not based on the chart itself but on "Guardant's exclusion of tissue-informed results from the [Parikh Study] or any marketing about Reveal despite its knowledge of those results." Opp. at 19 (citing Docket No. 94-10 (an email thread from Corcoran stating, "In taking a quick look through, it looks like applying a tumor-informed approach will be important in this cohort.")). Natera does not, however, reference any document in its allegations that "suggests a tumor-informed version of Reveal ever 'showed better performance'" as alleged. Reply at 3 (citing Am. Countercl. ¶ 85).

Thus, although Natera fails to sufficiently allege that Guardant hid data derived from tissue samples, it adequately pleads that the Parikh Study fraudulently described its methodology as a blinded analysis when Guardant used unblinded data and modified results to improve Reveal's performance. Its Lanham Act claim based on the allegation that the Parikh Study falsely describes itself as a blinded study is plausible. *See ONY*, 720 F.3d at 497; *Southland Sod Farms*, 108 F. 3d at 1139–40.

c. "Prospective" Study

Finally, the Parikh Study is allegedly fraudulent because it described its methodology as involving a "prospective" study even though Guardant manipulated the Study's methodology and data *post hoc*. Opp. at 20; Am. Countercl. ¶ 87. For example, as discussed above, [redacted] Am. Countercl. ¶ 87. [redacted] *Id.* In fact, [redacted] Docket No. 94-7 at 32. These allegations—that Guardant purportedly "eschew[ed] a clear statistical analysis plan (SAP) for the Study in favor of post hoc methods and analyses that could be manipulated, [redacted]

[redacted]" to falsely yield more favorable results—are plausible. Am. Countercl. ¶ 61 (quoting Docket No. 94-6 at 3); *see ONY*, 720 F.3d at 497 ("If the data were falsified, the fraud would not be easily detectable by even the most informed members of the relevant scientific community."); *Southland Sod Farms*, 108 F.3d at 1139–40.

Guardant's only response is based on a factual dispute—the definition of "prospective." *See* Reply at 11. According to Guardant, the audience would adopt the definition of "prospective," as defined by the FDA: "In prospective observational studies, investigators recruit subjects and observe them before a particular outcome occurs. In retrospective observational studies, investigators review the records of subjects and interview subjects after the outcome has occurred." *Id.* (citing FDA Adv. and Prom. Man. App'x II 237 (Sept. 2019 Supp.). It contends that the Parikh Study meets this definition because it recruited subjects for their study before the outcome of interest occurred and therefore it is accurately described as a "prospective observational study in patients with stage I to IV colorectal cancer treated with curative-intent therapy to assess the ability of a plasma-only ctDNA assay to identify patients with MRD who would ultimately recur." Parikh Study at OF2. But again, Guardant's contentions rely on factual disputes, *i.e.*, how the audience would understand "prospective" and how the term should be defined; because Natera's factual allegations must be accepted as true at this stage, its counterclaims are sufficiently pleaded. *See Southland Sod Farms*, 108 F.3d at 1140.

5. Conclusion

Accordingly, the Court **DENIES** Guardant's motion to dismiss Count I of Natera's Amended Counterclaims. Because Natera's California false advertising, unfair trade practices, and common law unfair competition claims are "substantially congruent" to claims made under the Lanham Act, the Court also **DENIES** Guardant's motion to dismiss Natera's state law claims, Counts II–IV. *See ThermoLife Int'l, LLC v. Compound Sols., Inc.*, 848 F. App'x 706, 709 (9th Cir. 2021) ("[S]tate common law claims of unfair competition are 'substantially congruent' to claims made under the Lanham Act, and thus share the same analysis."). As the Court was "not prepared to decide that the Challenged Statements are 'non-actionable,'" during the preliminary injunction stage, it is also not prepared to find Natera's counterclaims are "non-actionable" at the pleading

stage "before discovery and expert testimony is taken." *See* PI Order at 12.

B. Motion to Dismiss or Strike Counts V–VIII

Guardant also moves to dismiss or strike Natera's declaratory judgment counterclaims, which allege that Natera does not violate the Lanham Act and California's false advertising, unfair trade practices, and common law unfair competition statutes ("Counts V–VIII"). Reply at 15. A court "has complete discretion whether to hear a counterclaim for declaratory judgment." *Stickrath v. Globalstar, Inc.*, No. 07-CV-1941-TEH, 2008 WL 2050990, at *3 (N.D. Cal. May 13, 2008). "Numerous courts have used that discretion to dismiss counterclaims under [Rule] 12(f) where they are either the 'mirror image' of claims in the complaint or redundant of affirmative defenses." *Id.* But "it is not always appropriate to strike declaratory judgment counterclaims simply because they concern the same subject matter or arise from the same transaction as the complaint." *Id.* at *4. In deciding whether to strike a declaratory judgment counterclaim, a "court should focus on whether the counterclaims serve any useful purpose and should dismiss or strike a redundant counterclaim only when it is clear that there is a complete identity of factual and legal issues between the complaint and the counterclaim." *Id.* (internal citations and quotation marks omitted).

Guardant asserts that these declaratory judgments of non-liability are redundant because they mirror its affirmative claims. *Id.*; *compare* Am. Countercl. ¶¶ 153–54 ("Count V") (asserting that "Guardant's allegations that acts by Natera have violated Section 43(a) of the Lanham Act (as asserted in Guardant's complaint) have no basis in law or fact and fail to state a claim for relief," and seeking a "declaratory judgment that [Natera] does not violate Section 43(a) of the Lanham Act") *with* Compl. ¶ 61–63 (seeking damages and injunctive relief for violations of Section 43(a) of the Lanham Act).

Natera does not dispute that the claims are duplicative but it argues that Guardant must show prejudice to strike its claims. Opp. at 25. For the reasons above, however, a finding of prejudice is not necessary. Although, district "courts often require some showing of prejudice by the moving party," *Intel Corp. v. Tela Innovations, Inc.*, No. 18-CV-02848-WHO, 2019 WL 2476620, at *8 (N.D. Cal. June 13, 2019), the Ninth Circuit, in an unpublished decision, has

suggested that a showing of prejudice is not required in a Rule 12(f) motion.[4] *Atlantic Richfield Co. v. Ramirez*, 176 F.3d 481 (9th Cir. 1999) (unpublished) ("Rule 12(f) says nothing about a showing of prejudice and allows a court to strike material sua sponte.").

Because Natera's Counts VI–VIII are duplicative of Guardant's affirmative claims and there do not appear to have any useful purpose at this juncture, the Court **GRANTS** Guardant's motion to strike these counterclaims without prejudice.

IV. CONCLUSION

For the reasons explained above, the Court **DENIES** Guardant's motion to dismiss Natera's Counts I–IV. The Court **GRANTS** its motion to dismiss or strike Natera's Counts V–VIII without prejudice.

This order disposes of Docket No. 95.

IT IS SO ORDERED.

Dated: January 18, 2022

EDWARD M. CHEN
United States District Judge

United States District Court
Northern District of California

[4] The Ninth Circuit has not resolved the issue of whether prejudice is required in a Rule 12(f) motion. *See Basque v. Cty. of Placer*, 2017 WL 950503, at *2 (E.D. Cal. Mar. 10, 2017).